

Notice of Allowability	Application No.	Applicant(s)	
	10/058,022	RUNGE ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 14 November 2005.
2. ☒ The allowed claim(s) is/are 1-21.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. §1.114, the Amendment, Applicant's Arguments/Remarks and the Affidavit/Declaration, all filed 11/14/05 is acknowledged.

Claims 1-21 are pending in this action. New claim 21 has been added by virtue of the amendment. Claims 1-21 are allowed.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/05 has been entered.

EXAMINER'S AMENDMENT

The application has been amended as follows:

In the Specification:

On page 1, beginning on the first line after the title, the phrase, **“This application claims benefit to German foreign priority Application No. 10104494.1 filed January 31, 2001”** has been added.

In the Abstract:

A new abstract, contained in one single paragraph has been provided.

Allowable Subject Matter

Claims 1-21 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Jensen *et al.* – WO 91/06292; Horn *et al.* – U.S. Pat. No. 4,522,743 & Dobler *et al.* – WO 96/01570) does not disclose nor fairly suggest or teach the instant method of improving density and stability of a dry powder of one or more carotenoids comprising the process steps as claimed. More specifically, the prior art fails to disclose or teach a method of improving density and stability of a dry powder of one or more carotenoids as claimed using the particular combination of a soybean protein and lactose in the preparation of the dry powders. The prior art fails to disclose or teach the instant method of improving density and stability of a dry powder of one or more carotenoids comprising a) dispersing the one or more carotenoids in an aqueous or molecular solution of a mixture comprising effective amounts of lactose and a protective colloid and converting the dispersion formed in step (a) into a dry powder by removing water and additional solvents, wherein at least one soybean protein is used as a protective colloid. In contrast, the prior art discloses the use of

the sugar glucose rather than lactose as claimed. Applicants have fully demonstrated that the use of lactose, of which the prior art is deficient, is a critical feature of their invention, which offers distinct advantages over that of the art.

Applicant has submitted a declaration filed 11/14/05, which sets forth comparative data that provides that the particular combination of a soybean protein and lactose in the preparation of dry powders provides for a product which exhibits distinct superior properties over the processes of the prior art. The declaration demonstrates that the superior properties are not achieved when either the soybean protein is replaced by another colloid (*i.e.*, casein, gelatin) or when the lactose is replaced by another sugar (*i.e.*, glucose). The declaration submitted by Applicant effectively shows that the nature of the protective colloid and sugar employed impacts the storage stability of the carotenoid dry powder. In the declaration filed 11/14/05, on page 2, Sample (A) represents the instant invention's formulation, using soybean protective colloid and lactose as the sugar. The example clearly demonstrates that the carotenoid loss upon storage (%) is much less (16.5%) than other formulations which result in >30% carotenoid loss using a different protective colloid (*i.e.*, casein) and/or different sugar (*i.e.*, glucose). Thus, the instant invention demonstrates an improvement over prior art formulation processes through the use of lactose in combination with a soybean protective colloid, because it provides for increased stability of dry powder carotenoid formulations versus formulations employed by the prior art. Hence, in view of the improvements of the instant invention and the lack of teachings of the prior art, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

February 02, 2006

hns

Humera N. Sheikh
TC-1600

Abstract

The invention relates to a process for producing dry powders of one or more carotenoids by a) dispersing one or more carotenoids in an aqueous molecular or colloidal solution of a mixture of lactose and a protective colloid and b) converting the dispersion which has formed into a dry powder by removing the water and, where appropriate, additionally used solvents and drying, where appropriate in the presence of a coating material, wherein at least one soybean protein is used as protective colloid in process step a).